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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,243	11/12/2003	Solomon S. Steiner	PDT 103 CON(3)	6406
23579 7590 10/01/2007 PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE, SUITE 1200 1201 PEACHTREE STREET ATLANTA, GA 30361			EXAMINER GEORGE, KONATA M	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/706,243

Applicant(s)

STEINER ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16, 18-27, 31, 32 and 36-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-27, 31, 32 and 36-51 is/are allowed.
- 6) ☒ Claim(s) 16, 18, 22 and 52-54 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/28/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 16, 18-20, 21-27, 31, 32 and 36-54 are pending in this application.

#### ***Action Summary***

1. The examiner acknowledges the cancellation of claims 17, 21, 28-30 and 33-35. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.
2. The rejection of claims 16 and 36 under 35 U.S.C. 103(a) as being unpatentable over Boyes et al. is hereby withdrawn in view of applicants amendment to the claims. The rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over Boyes et al. in view of Hunt et al. is hereby withdrawn in view of applicants amendment to the claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 16, 18, 22 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sankaram et al. (US 6,132,7666).

Applicants claim dry microparticle having a size range between 0.5 and 10 microns containing a drug, wherein the microparticles are formed of a material releasing the drug at a pH of 6.0 or greater and wherein the material is selected from the group consisting of alginate, chitosan, hydrophobic or hydrophilic proteins and lipids.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Sankaram et al. disclose a microparticle comprised of lipids having a diameter of 1-100 microns (col. 5, lines 3-20 and figure 1). Column 5, lines 45-62 teach the list of classes of biologically active substances that can be used in the microparticles.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Sankaram et al. do not teach the pH or the specific drugs as claimed by applicant. It is not taught by Sankaram et al. to place the particles in a cartridge for insertion into an inhaler.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

With respect to the pH of the material, it is the position of the examiner that since Sankaram et al. teach the same material as claimed, then the material would have the same inherent properties of releasing the drug at the claimed pH. The claim merely states that the microparticle is formed from a material that has that limitation, so any material that is claimed by applicant (i.e. lipids) would have that limitation as well. With respect to the specific drugs, it is the position of the examiner that the table provided in column 5, lines 45-62 incorporates all drugs of a particular class. For example under the class of hormones, all hormones such as estrogen, LHRH, etc. would fall within the limitation and would be obvious. When formulating the composition for delivery to the lungs, it would have been obvious to one of ordinary skill in the art, to place the composition into storage capsules or cartridges for use in inhalers to deliver the composition to the patient.

***Allowable Subject Matter***

4. Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art reference of Sankaram et al. do not teach, disclose or suggest the microparticle material comprising a material selected from the group consisting of alginate, chitosan, hydrophobic or hydrophilic proteins.

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5. Claims 23-27, 31, 32 and 36-51 are allowed. The prior art does not disclose, teach or suggest a method of administering to a patient microparticles comprising diketopiperazine and an active agent. It is not disclosed, taught or suggest to formulate the microparticles comprising the polymers claimed in claims 30, 32 and 50. It is also not taught to use add a diketopiperazine compound to the particles.

***Conclusion***

6. Claims 16, 18, 22 and 52-54 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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